and also requests comments on the contaminants selected, including any supporting data that can be utilized in developing the final CCL 3. A number of contaminants considered for the draft CCL 3 may be of particular current interest. The following sections provide information for a few of the contaminants that are of most interest. Data obtained and evaluated for developing the draft CCL 3 and referred to in the following sections may be found in the docket for this notice. Specifically, the Agency is also asking for public comments on pharmaceuticals and perfluorinated compounds to identify any additional data and information on their concentrations in finished or ambient water and requests comment on how they have been considered in the CCL 3 process. The Agency is also seeking additional data and information on the occurrence and health effects of *H. pylori* and how this pathogen was considered in the CCL 3 process. Information and comments submitted will be considered in determining the final CCL 3, as well as in the development of future CCLs and in the Agency's efforts to set drinking water priorities in the future.

A. Pharmaceuticals

The Agency evaluated data sources to identify pharmaceuticals and personal care products that have the potential to occur in PWSs. The primary source of health effects information on pharmaceuticals in the universe was the Food and Drug Administration Database on Maximum Recommended Daily Doses (MRDD). This database includes the recommended adult doses for over 1,200 pharmaceutical agents. Occurrence information from USGS Toxics Substances Hydrology program's National Reconnaissance of Emerging Contaminants, and related efforts, provided ambient water concentration data for 123 contaminants, which include pharmaceuticals. Other data sources included TRI and high production volume chemical data. From this analysis, EPA included 287 pharmaceuticals in the Chemical Universe. These pharmaceuticals had maximum recommended daily dose information that EPA used to evaluate adverse health effects. EPA considered those pharmaceuticals for which MRDD values and occurrence information were available and pharmaceuticals that were in Toxicity Category 1, using the same criteria discussed in Section III.A.2.a. EPA found that less than two percent of the pharmaceuticals included in the MRDD database fell into this category.

EPA applied the LOAEL screening protocols to contaminants with MRDD values. The LOAEL protocol was used because pharmaceutical agents, although used for their beneficial effects, have associated side-effects that may be adverse. Chemicals evaluated with these data had similar modal values and distributions to the toxicity values from IRIS. The range of toxicity values in this database covered 9 orders of magnitude when evaluated based on their rounded logs. They had the same modal value as the LOAELs from IRIS and a very similar distribution. Thirty-five percent of the IRIS LOAELS and 38 percent of the MRDDs had the modal rounded log. Thirty-three percent of the LOAELs and 19 percent MRDDs had rounded logs that were lower than the mode, while 31 percent of the LOAELs and 44% of the MRDDs had rounded logs that were above the modal log value.

The screening process moved approximately 10 percent of the pharmaceuticals in the Universe to the PCCL. All toxicity data on those chemicals were included in the screening with the most serious qualitative or quantitative measure of toxicity determining placement in a toxicity category. Only one of the PCCL chemicals (diazinon, a veterinary product as well as a pesticide) had water concentration data. Two other pharmaceuticals: phenytoin (an anticonvulsant) and nitroglycerin (treatment of angina), had release data. The remainder were scored for occurrence based on production information, which meant that they fell into the low certainty bin for their occurrence parameters. Nitroglycerin is the only pharmaceutical that is included on the draft CCL 3. EPA is aware of concerns regarding the potential presence of pharmaceuticals in water supplies. The Agency is seeking additional data and information on the concentrations of pharmaceuticals in finished or ambient water and requests comment on how pharmaceuticals have been considered in the CCL 3 process.

B. Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid

EPA evaluated perfluorinated compounds in the CCL 3 process and requests comment on its decisions to include perfluorooctanoic acid (PFOA) and not to include perfluorooctane sulfonic acid (PFOS) on the draft CCL 3. EPA identified potential health effects and occurrence information for these compounds from the data sources discussed in Section III. The data used for these compounds are discussed in the support documents in more detail. Available analytic methods for these chemicals limited the occurrence data for these compounds. The Agency identified data on the annual production from CUS/IUR indicating limited production and possible release to the environment. Several organizations nominated PFOS and PFOA for consideration in the CCL process. The nominations noted that these chemicals are persistent in the environment and have been detected at varying levels in drinking water and ambient water in smaller specialized studies. EPA collected the information cited in the nominations and evaluated each of these chemicals. The Agency included PFOA on the draft CCL 3 because it met the criteria for inclusion on draft CCL 3 based on drinking water occurrence studies in Ohio and West Virginia (Emmett, *et al.*, 2006) and on health effects data indicated through animal studies (USEPA, 2005 a).

The Agency did not include PFOS on the draft CCL 3. Occurrence data for PFOS characterized detections in several States (Boulanger, *et al.*, 2004, Hansen, *et al.*, 2002, Goeden and Kelly, 2006). These data showed that levels of detection for PFOS in ambient water ranged from 20 to approximately 100 parts per trillion. Data identified in the nominations process detected PFOS at higher concentrations in areas surrounding landfills known to be contaminated with industrial waste containing PFOS. The CCL process did not consider occurrence data from targeted studies of contaminated waste sites, however. Such studies are usually developed to identify and characterize hazardous waste cleanup efforts and may not be representative of occurrence in drinking water not in close proximity to the study site. PFOS was phased out of production in the U.S. between 2000 and 2002, and regulation limits its importation to a very small number of controlled, very low

release uses, (67 FR 72854; December 9, 2002 (USEPA, 2002 c)). Based on the general absence of occurrence data, combined with the phase out, effectively eliminating most future releases, PFOS did not meet the criteria for CCL 3.

The Agency is evaluating data related to PFOA in a formal risk assessment process under the Toxic Substance Control Act. EPA's Science Advisory Board (SAB) completed a review of a draft risk assessment in 2006 and SAB made recommendations for the further development of the risk assessment. A final risk assessment may not be completed for several years, as a number of important studies are underway. The Agency is also participating in additional research regarding the toxicity and persistence of related perfluorochemicals, as well as research to help identify where these chemicals are coming from and how people may be exposed to them.

C. Helicobacter pylori

Helicobacter pylori is a pathogen that causes gastric cancer in addition to acute gastric ulcers. EPA placed this pathogen on the draft CCL. However, the analysis for *H. pylori* differs from the other pathogens due to the long term and/or chronic nature of its health effects rather than the more common acute effects of most waterborne pathogens. This organism is an emerging pathogen whose impact has only recently begun to be understood. Given the slow development of adverse health effects due to infection by *H. pylori*, it is more difficult to link contamination of drinking water and show a waterborne disease outbreak. Therefore, given the long timeframe of cancer and ulcer development (as opposed to the commonly acute gastrointestinal illness of nearly all the other pathogens on the PCCL) as well as the ongoing nature of the research, EPA used peer-reviewed scientific papers to score the health effects of *Helicobacter pylori*. EPA request comment on the process of selection of microbial contaminants that cause chronic rather than acute health effects.

V. EPA's Next Steps

Between now and the publication of the final CCL, the Agency will evaluate comments received during the comment period for this notice, consult with the SAB, and re-evaluate the criteria used to develop the draft CCL and revise the CCL, as appropriate.

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